



Perry Johnson Laboratory Accreditation, Inc.

APPLICATION / QUESTIONNAIRE
ISO 15189-Medical Laboratory
 (Strictly Confidential)

1. Name and address of laboratory (this is the name and address which will appear in the PJLA, Inc., Accreditation Services Directory, etc.)			
Company Name			
Address Line 1			
Address Line 2			
City	State/Region	Zip Code	Country
Phone	URL	E-Mail	
2. Name and address of parent organization (if different from above). Will this parent organization be part of the accreditation? _____ Yes _____ No			
Company Name			
Address Line 1			
Address Line 2			
City	State/Region	Zip Code	Country
Phone	URL	E-Mail	
3. Name of Laboratory Director of applicant.			
Name			
Phone 1	Phone 2	E-Mail	
4. Name, position of Organization's/Laboratory's Liaison with PJLA, Inc.			
Name		Title	
Phone 1	Phone 2	E-Mail	
5. Number of staff employed by organization: Testing Staff ____ Support Staff ____ Laboratory Director(s) ____ Total ____			
6. Is this Lab internal to a larger company doing other activities? _____ Yes _____ No (If the answer to 6 is yes, answer a thru e . If no, proceed to section 7)			
a. Are there other activities than the main activities? _____ Yes _____ No			
b. Describe the nature of the other activities:			

c. Does the laboratory undertake testing for its own organizations?	___ Yes ___ No
d. Does the laboratory undertake testing for outside organizations?	___ Yes ___ No
e. Enclose an organization chart showing the outline of the organization and the chain of command from the highest executive at that location down to the laboratory head.	
7. Has the organization been assessed by any other accreditation bodies in the past? ___ Yes ___ No (If the answer to 6 is yes, answer a and b . If no, proceed to section 8)	
a. Please indicate the type and date of last assessment, which covered the activities included in this application, and enclose copies of the most recent certificate. (attach list if needed)	
Type _____	Date _____
Type _____	Date _____
b. Explain the reason for seeking transfer of accreditation (i.e. cost, service etc.) _____	
8. Is your facility interested in a pre-assessment?	___ Yes ___ No
9. Are you currently working with a consultant to prepare for accreditation?	___ Yes ___ No
10. Please indicate your target date to achieve accreditation by. _____	

How did you hear about PJLA? <input type="checkbox"/> Website <input type="checkbox"/> Referral <input type="checkbox"/> Tradeshow <input type="checkbox"/> Social Media <input type="checkbox"/> Other	
COMPLETED BY:	
Signature	_____
Name	_____
Title	_____
Date	_____
Return to:	Perry Johnson Laboratory Accreditation, Inc. / Attn: President/Operations Manager 755 W. Big Beaver Road, Suite 1325 Troy, MI 48084 email to: pjlabs@pjlabs.com fax: (248) 213-0737

Following this section are annexes in order to inform PJLA of the types of tests to be included on your scope of accreditation. At minimum Annex A must be completed. Annex B-E only need to be completed as they apply to your organization and if you are seeking accreditation for these additional areas. Annex F- is for information only, but should be completed if applicable.

Application Terms

In the following Annexes please complete the fields of tests including the discipline, process of examination, product (sample or specimen), property, parameter, and measurement technique. Below are definitions for these areas to assist with completing the application as accurately as possible.

Discipline	Medical laboratory testing area
Process of Examination	Specific test or examination being performed
Property	The item that is being measured, determined or identified
Test Sample	The portion of a specimen subjected to the test procedure, e.g. product of pre-analytical processing, specimen type, specimen source.
Parameter (Range)	A numerical or other measurable factor of a system which sets the conditions of its operation
Measurement Techniques	The methodology of the test which detects, quantifies, or identifies the property, including any pre-analytical processes to present the sample to the measuring device (e.g. PCR).

Disciplines	Microbiology	Hematology	Radiobioassay	Chemistry
	Bacteriology	Immunoematology	Cytology	Endocrinology
	Mycology	ABO and Rh typing	Histocompatibility	Toxicology
	Mycobacteriology	Anatomic Pathology	Cytogenetics	Urinalysis
	Parasitology	Histopathology	Molecular Pathology	Immunology

Example Scope of Accreditation:

Discipline	Process of Examination	Test Sample	Property	Parameter/Range	Measurement Techniques / Instrument
Immunology	Serum Protein Immunology	Serum	CRP	-	-
Hematology	Blood Functional Test	Blood	HbA1c	4.5% to 10.0% NGSP	EIA (Hitachi 7050)
Microbiology	Urine Culture & Identification	Urine	Pathogens (e.coli)	Presence/Absence	VITEK
Biochemistry	Enzymes	Serum	γ G T	CV _A : 8.2%, B _A : 12.8%	IFCC Traceable Method (Hitachi 7050 Type)
Hematology	Blood Test	Blood	RBC	CV:4.1%	See-Through Method (Sysmex XN-550)

ANNEX A – Testing (Fixed Laboratory)

Additional sheets for tests obtaining accreditation for may be required to be completed. For Branch, Satellite, or Mobile Units etc., please see additional annexes within this application.

Discipline	Process of Examination	Test Sample	Property	Parameter / Range	Measurement Techniques / Instrument

ANNEX B –Branch Clinical Lab

Additional laboratories owned and operated by the same organization, utilizing the same management system, and managed by a Corporate Representative

Please indicate address of branch office if different than the main location: _____

Please specify approximate distance from main location: _____

Please indicate the number of technicians at the location: _____

Discipline	Process of Examination	Test Sample	Property	Parameter / Range	Measurement Techniques / Instrument

ANNEX C –Satellite Clinical Lab

Laboratory is on the same campus or in the same contiguous building as the main laboratory, operates under the same management system as the main laboratory, can have prompt supervisory oversight from the main laboratory, when necessary, and has appropriate oversight from the same laboratory director that represents the main laboratory

Please indicate address of branch office if different than the main location: _____

Please specify approximate distance from main location: _____

Please indicate the number of technicians at the location: _____

Discipline	Process of Examination	Test Sample	Property	Parameter / Range	Measurement Techniques / Instrument

ANNEX D –Mobile Clinical Labs

Mobile Clinical Labs- Fully equipped, self-contained, transportable clinical testing laboratory capable of performing clinical tests under controlled environmental conditions. A mobile laboratory may perform testing only when the laboratory is stationary. Mobile clinical laboratories left at one location for three years are considered permanent laboratories

Please indicate VIN # of the mobile lab(s): _____

Please specify approximate distance from main location: _____

Please indicate the number of technicians at the location: _____

Discipline	Process of Examination	Test Sample	Property	Parameter / Range	Measurement Techniques / Instrument

ANNEX E – Point of Care (POCT) Testing Labs

Facilities where tests are being performed at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside of the physical facilities of the clinical laboratory.

Please indicate the address of the POCT lab: _____

Please specify approximate distance from main location: _____

Please indicate the number of technicians at the location: _____

Discipline	Field of Tests	Test Sample	Property	Parameter / Range	Measurement Techniques / Instrument

ANNEX F-In-house Calibration

Calibration (for which the organization is not seeking accreditation for) performed internally that directly affect the traceability of the calibration and/or test results (See PL-2 PJLA Traceability Policy). (This section potentially applies to both calibration organizations and Testing organizations calibrating their own equipment)

In the table below, please specify any calibrations you perform of your own equipment for purposes of conducting the calibrations or tests for which you are seeking accreditation. By definition these will be calibrations for which your organization is not accredited. Continue on additional supplementary sheets, if necessary. From this information, we can better determine how much time on-site is necessary to evaluate your laboratory.

CALIBRATION FIELD	MEASURED QUANTITY, INSTRUMENT OR GAUGE	RANGE OR NOMINAL DEVICE SIZE AS APPROPRIATE	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
<i>EXAMPLE-Mass Calibration</i>	<i>Analytical Balance</i>	<i>1 mg to 200 g</i>	<i>(0.013 + 0.003Wt)</i>	<i>Class 1 weights</i>